K082412

NOV 10 2008

MAQUET

510 (K) Summary [as required by 21 CFR 807.92(c)]

Submitter:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person:	Katrin Schwenkglenks Phone: +49 7478 921-151 Fax: +49 7478 921-400 E-mail: katrin.schwenkglenks@maquet-cp.com
Date Prepared:	August 20, 2008
Device Trade Name:	Venous Bubble Trap with and without Bioline Coating
Common/Usual name:	Venous Bubble Trap
Classification name:	Cardiopulmonary bypass bubble detector
Predicate Devices:	Quadrox D Diffusion Membrane Oxygenator with Bioline Coating, Maquet Cardiopulmonary AG (K071774), Capiox Bubble Trap, Terumo Medical Corp. (K911632), the Ideal Mimesys Venous Air Removal Device from Dideco S.r.l. as part of the Ideal Mimesys System (K032040) and the ECC.O System with Integrated Venous Air Removal from Dideco S.r.l. (K050890) which does also contain a venous bubble trap as component.

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Device Description:

The Venous Bubble Trap is a sterile and non-pyrogenic device, for single use only and is not to be re-sterilized by the user. The device is sterilized with Ethylene Oxide.
The bubble trap is intended for use in an extracorporeal circulation system during a cardiopulmonary bypass within the framework of surgical intervention. Within the specified flow rate limits, the bubble trap separates macroscopic air bubbles from the venous line, eliminating them through the deaeration line and out of the extracorporeal circulation. The device is to be used for up to 6 hours.

Indications for Use:

The bubble trap is intended for use in an extracorporeal circulation system during a cardiopulmonary bypass within the framework of surgical intervention. Within the specified flow rate limits, the bubble trap separates macroscopic air bubbles from the venous line, eliminating them through the deaeration line and out of the extracorporeal circulation, and by doing so supports the perfusionist's obligation to exercise due caution. The product must not be used for more than 6 hours at a time. The physician in charge of treatment must make all decisions concerning use of the venous bubble trap.

Statement of Technical Comparison:

The Venous Bubble Trap with and without Bioline Coating has the same design, principals of operation, and performance as the predicate device on the market. The Bioline Coating is the same as cleared with the Quadrox D Diffusion Membrane Oxygenator with Bioline Coating.

Non-clinical Testing:

The following areas have been tested:

- Integrity
- Performance
- Stability of the Coating
- Biocompatibility
- Sterility

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Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was executed to demonstrate that the Venous Bubble Trap with and without Bioline Coating described in this submission is substantially equivalent to the Capiox Bubble Trap from Terumo Medical Corp. as a bubble trap as well as with the Quadrox D Diffusion Membrane Oxygenator with Bioline Coating with regards to the coating.

Conclusion

The data given demonstrate that the Venous Bubble Trap with and without Bioline Coating is substantially equivalent to the named predicate devices which currently hold market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Official Correspondent
Hechinger Strassue 38
Hirrlingen, Germany 72145

Re: K082412
Venous Bubble Trap with and without Bioline Coating
Regulation Number: 21 CFR 870.4230
Regulation Name: Cardiopulmonary bypass defoamer
Regulatory Class: Class II
Product Code: DTP
Dated: October 17, 2008
Received: November 3, 2008

Dear Ms. Schwenkglenks

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082412

Device Name: Venous Bubble Trap with and without Bioline Coating _____

Indications for Use:

The bubble trap is intended for use in an extracorporeal circulation system during a cardiopulmonary bypass within the framework of surgical intervention. Within the specified flow rate limits, the bubble trap separates macroscopic air bubbles from the venous line, eliminating them through the deaeration line and out of the extracorporeal circulation, and by doing so supports the perfusionist's obligation to exercise due caution.

The product must not be used for more than 6 hours at a time.

The physician in charge of treatment must make all decisions concerning use of the venous bubble trap.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochniak

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082412

(Posted November 13, 2003)